REMARKS

Reexamination and reconsideration of the application as amended are requested. Support for the new claims is found, for example, from paragraphs [0027] and [0033] of the specification.

The examiner's rejection of claims 1, 3, 6 and 8 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel (US 5,413,550) in view of Watkin (non-patent literature).

The examiner, in the advisory action, stated that ".. it would have been obvious ... to have modified Castel by using experimentally-determined in vitro treatment parameters in order to determine in vivo treatment parameters, as taught by "Watkin, in the function disclosed by Castel ...".

Castel determines frequency, ultrasound intensity (power), and treatment time as a function of tissue depth, a tissue temperature increase, a treatment area, a couplant selection, and optionally a tissue type and a duty factor. See the abstract and column 8, line 68 to column 9, line 9 of Castel. It is noted that the actual function of Castel is not disclosed, but the treatment parameters (tissue depth, tissue temperature increase, etc.) used in the function are disclosed. It is clear that the treatment parameters used in the function of Castel of tissue depth, a tissue temperature increase, treatment area, and tissue type are in vivo treatment parameters.

Is the examiner suggesting, from Watkin, that it would have been obvious to have Castel determine in vivo tissue depth from in vitro tissue depth, determine an in vivo tissue temperature increase from an in vitro tissue temperature increase, determine in vivo treatment area from in vitro treatment area, and determine in vivo tissue type from in vitro tissue type? That would only result in Castel determining in vivo frequency, in vivo ultrasound intensity (power), and in vivo treatment time as a function of in vitro tissue depth, an in vitro tissue temperature increase, an in vitro treatment area, a couplant selection, an in vitro tissue type, and a duty factor. Therefore, Castel would not be determining an in vivo treatment time as a function of the in vitro treatment time as required by claims 1-2 and 6-7, and Castel would not be determining an in vivo

ultrasound acoustic power as a function of the in vitro ultrasound acoustic power as required by claims 3-4 and 8-9.

Or, is the examiner suggesting, from Watkin, that it would have been obvious for Castel to determine in vivo treatment time from in vitro treatment time as taught by Watkin and to determine in vivo ultrasound acoustic power from in vitro ultrasound acoustic power as taught by Watkin?

Such later suggestion would only result in always using an in vivo treatment time being equal to the in vitro treatment time wherein the in vitro treatment time is always approximately 3 seconds or less to avoid the effects of in vivo blood perfusion not present with in vitro tissue (see the paragraph which begins near the bottom of the second column of page 194 and ends on the first column of page 195 of Watkin). Watkin's function of relating in vivo treatment time to in vitro treatment time is simply that in vivo treatment time equals in vitro treatment time when the in vitro time is approximately 3 seconds or less. It is noted that Watkin does not teach, suggest, or describe in vivo treatment time as a function of in vitro treatment time when the in vitro treatment time is greater than approximately 3 seconds. The teaching of Watkin that $time^{in\ vivo} = time^{in\ vitro}$ when $time^{in\ vitro}$ is approximately 3 seconds or less is teaching that $time^{in\ vivo}$ equals a function of $time^{in\ vitro}$ when $time^{in\ vitro}$ is approximately 3 seconds or less, wherein the function is the number 1 (unity). The number 1 (unity) is not a blood perfusion rate. The in vivo treatment time of Watkin is not a function of the in vitro treatment time, wherein the function includes a blood perfusion rate. The unity function of Watkin does not include a blood perfusion rate. It is also noted that "an in vitro treatment time of 3 seconds or less" in not a blood perfusion rate. Watkin does not teach, suggest, or describe an in vivo treatment time as a function of in vitro treatment time, wherein the function includes blood perfusion rate and patient tissue density as required by applicant's claims 2-3 and 6-7. Therefore, Castel, using the method of Watkin, would likewise fail to teach, suggest, or describe an in vivo treatment time as a function of in vitro treatment time, wherein the function includes blood perfusion rate and patient tissue density as required by applicant's claims 2-3 and 6-7.

Such later suggestion also would result in always using (together with the approximately 3 seconds or less treatment time) an in vivo ultrasound acoustic power equal to the in vitro ultrasound acoustic power, wherein the maximum in vitro ultrasound acoustic power is always less than 1500 Wcm^{-2} to avoid lesions which form in front of the focus and which are unpredictable in their size and shape (see the first full paragraph in the first column of page 195 of Watkin). The teaching of Watkin that $q^{in\ vivo} = q^{in\ vitro}$ wherein the maximum $q^{in\ vitro}$ is less than 1500 Wcm^{-2} is teaching that $q^{in\ vivo}$ equals a function of $q^{in\ vitro}$ wherein the maximum $q^{in\ vitro}$ is less than 1500 Wcm^{-2}, wherein the function is the number 1 (unity). The number 1 (unity) is not a blood perfusion rate. The in vivo ultrasound power of Watkin is not a function of the in vitro ultrasound power, wherein the function includes a blood perfusion rate. The unity function of Watkin does not include a blood perfusion rate. It is also noted that "wherein the in vitro ultrasound acoustic power is always less than 1500 Wcm^{-2} " is not a blood perfusion rate. Watkin does not teach, suggest, or describe an in vivo ultrasound acoustic power as a function of in vitro ultrasound acoustic power, wherein the function includes blood perfusion rate and patient tissue density as required by applicant's claims 4-5 and 8-9. Therefore, Castel, using the method of Watkin, would likewise fail to teach, suggest, or describe an in vivo ultrasound acoustic power as a function of in vitro ultrasound acoustic power, wherein the function includes blood perfusion rate and patient tissue density as required by applicant's claims 4-5 and 8-9.

The examiner's rejection of claims 2, 4, 7 and 9 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel in view of Watkin and further in view of page 260 of Hill (non-patent literature). Claim 2 depends from claim 1, claim 4 depends from claim 3, claim 7 depends from claim 6, claim 9 depends from claim 8, and applicants' previous remarks concerning the patentability of claims 1, 3, 6 and 8 over Castel in view of Watkin are herein incorporated by reference.

Claims 2 and 7 require a specific equation mathematically relating the in vivo treatment time to form an in vivo lesion to the in vitro treatment time to form an in vitro lesion. The specific equation of clams 2 and 7 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 2 and 7 is not taught by page 260 of Hill because no equation

or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo treatment time to in vitro treatment time. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

Claims 4 and 9 require a specific equation mathematically relating the in vivo ultrasound acoustic power to form an in vivo lesion to the in vitro ultrasound acoustic power to form an in vitro lesion. The specific equation of clams 4 and 9 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 4 and 9 is not taught by page 260 of Hill because no equation or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo ultrasound acoustic power to in vitro ultrasound acoustic power. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

It is noted that new claims 11-14 require treatment times much greater than the approximately 3 second treatment-time upper limit of Watkin.

Inasmuch as each of the rejections has been answered by the above remarks and amended claims, it is respectfully requested that the rejections be withdrawn, and that this application be passed to issue. The Commissioner is authorized to charge any additional fees required or to credit any overpayment to Deposit Account No. 20-0809.

Respectfully submitted,

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